

16083848

APR 14 2009

Section 5 – 510(k) Summary or 510(k) Statement

I. General Information

Submitter: Alma Lasers, Ltd.
Halamish Street (PO Box 3021), Industrial Park,
Caesarea, 38900
ISRAEL

Contact Person: Tatiana Epstein
Regulatory Affairs Manager,
Alma Lasers, Ltd.

Summary Preparation Date: December 20th, 2008

II. Names

Device Names: Alma Lasers Soprano XL Multi-Application Platform

Primary Classification Names: Laser Instrument, Surgical, Powered

III. Predicate Devices

- K001746 - LightSheer Pulsed Diode Array Laser System Lumenis, Inc. (formerly Coherent Star)
- K003614 - LightSheer Pulsed Diode Array Laser System Lumenis, Inc. (formerly Coherent Star)
- K013028 - Palomar SLP™ 1000 – Palomar Medical Technologies, Inc.
- K050900 - MeDioStar XL – Asclepion Laser technologies, GmbH.
- K052874 - Soprano Hair Removal Diode Laser System – Alma Lasers, Ltd. (formerly MSq., Ltd.)
- K053628 – LightSheer Duet™ Laser System – Lumenis, Inc.

IV. Product Description

The **Soprano XL** Multi-Application Platform features an additional indication for the treatment of benign vascular and pigmented lesions introduced to its **Diode Module** compared to the existing Alma Lasers, Ltd. (former MSq., Ltd.) **Soprano** Diode Laser System, previously cleared under K052874 for hair removal and long-term hair reduction. The Soprano XL system is indicated for use on all skin types (Fitzpatrick Skin Types I-VI), including tanned skin.

The **Soprano XL** Multi-Application Platform is a multi-application, multi-technology platform that supports the following technologies:

- Diode laser technology
- Near-infrared light technology (NIR)².

² The Soprano XL NIR Module is cleared separately under K080318.

Both the Soprano and Soprano XL systems consist of a console, a diode module and a footswitch. The module is pressed against the patient skin and a laser pulse is delivered when the module trigger and the footswitch are activated. The module tip is cooled by the cooling system.

Output parameters and other system features are controlled from the touch-screen control panel on the console, which provides an interface to the system micro-controller through an LCD touch-screen.

V. Indications for Use

The **SOPRANO XL™ Multi-Application Platform** includes a Diode Laser Module and an optional NIR Module.

The Diode Laser Module:

The HR Mode is intended for hair removal, permanent hair reduction.

The LaserBlanche Mode is intended for the treatment of benign vascular and pigmented lesions.

The **NIR Module** is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

The SOPRANO XL™ Multi-Application Platform is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

VI. Rationale for Substantial Equivalence

The Alma Lasers Soprano XL Multi-Application Platform shares the same indications for use, the operation, technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Alma Lasers Soprano XL Multi-Application Platform is substantially equivalent to the predicate devices.

VIII. Conclusion

The Alma Lasers Soprano XL Multi-Application Platform was found to be substantially equivalent to the predicate devices.

The Alma Lasers Soprano XL Multi-Application Platform shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2009

Alma Lasers, Ltd.
% Ms. Tatiana Epstein
RA Manager
Halamish Street, P.O. Box 3021
Industrial Park
Caesarea 38900
Israel

Re: K083848

Trade/Device Name: Alma Lasers Soprano XL™ Multi-Application Platform
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 24, 2009
Received: March 26, 2009

Dear Ms. Epstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083848

Device Name: Alma Lasers Soprano XL™ Multi-Application Platform

Indications for Use:

The SOPRANO XL™ Multi-Application Platform includes a Diode Laser Module and an optional NIR Module.

The Diode Laser Module:

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Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil A. B. [Signature]
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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